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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,218	03/10/2004	Marcel Thürk	02198/0200973-US0	3485

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EXAMINER

LEE, STEPHEN JAE

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/798,218	Applicant(s) THURK, MARCEL	
	Examiner Stephen J. Lee, Ph.D.	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,17-19,23-26,50-52,56-59,82-84,88-91,117-119,123-126,163-165 and 169-171.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,17-19,23-26,50-52,56-59,82-84,88-91,117-119,123-126,163-165 and 169-171.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 17, 18, and 24, drawn to a compound or composition of formula I recited in claim 1, and pharmaceutically acceptable salts thereof, classified in class 530, subclass 300.
- II. Claims 26, 50, 51, and 57, drawn to a compound or composition of formula II recited in claim 26, and pharmaceutically acceptable salts thereof, classified in class 530, subclass 300.
- III. Claims 59, 82, 83, and 89, drawn to a compound or composition of formula III recited in claim 59, and pharmaceutically acceptable salts thereof, classified in class 530, subclass 300.
- IV. Claims 91, 117, 118, and 124, drawn to a compound or composition of formula IV recited in claim 91, and pharmaceutically acceptable salts thereof, classified in class 530, subclass 300.
- V. Claims 126, 163, 164, and 170, drawn to a compound or composition of formula V recited in claim 126, and pharmaceutically acceptable salts thereof, classified in class 530, subclass 300.
- VI. Claims 19, 23, and 25, drawn to a method of administering an effective amount of a compound according to claim 1, classified in class 514, subclass 2.

- VII. Claims 52, 56, and 58, drawn to a method of administering an effective amount of a compound according to claim 26, classified in class 514, subclass 2.
- VIII. Claims 84, 88, and 90, drawn to a method of administering an effective amount of a compound according to claim 59, classified in class 514, subclass 2.
- IX. Claims 119, 123, and 125, drawn to a method of administering an effective amount of a compound according to claim 91, classified in class 514, subclass 2.
- X. Claims 165, 169, and 171, drawn to a method of administering an effective amount of a compound according to claim 126, classified in class 514, subclass 2.

Inventions I-V are unrelated. There is no core sequence shared between the formulas recited in claims 1, 26, 59, 91, and 126. Unless the applicant can show otherwise, inventions I-V are different by virtue of their structure, therefore the applicant is required to elect one group for examination.

Inventions VI-X are unrelated. These methods of administering an effective amount of a compound encompassed by formulas I-V are different because they depend on the formulas that differ by virtue of their structure.

Inventions I-V and VI-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

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the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, non-peptide small molecule drugs like aspirin can be used in place of inventions I-V to inhibit thrombin in human and animals, for example.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Should a Group be elected, a further election of species is required.

This application contains claims directed to the following patentably distinct species of the claimed invention: different organic compounds of formulas I-V, as recited in claims 1, 26, 59, 91 and 126, respectively, encompassing groups Y^1 , $(NH-X^1-C=O)$, $(NH-X^2-C=O)$, $(NH-X^3-C=O)$, $(NH-X^4-C=O)$, $(NH-X^5-C=O)$, $(NH-X^6-C=O)$, and Y^2 . Each compound representing the formulas I-V within the scope of the recited claims is patentably distinct by virtue of their structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-171 are generic. The applicant is advised to select a single formula, and where necessary, the formula elected must be defined specifically by selecting each Y^1 , $(NH-X^1-C=O)$, $(NH-X^2-C=O)$, $(NH-X^3-C=O)$, $(NH-X^4-C=O)$, $(NH-X^5-C=O)$, $(NH-X^6-C=O)$, and Y^2 group from the groups set forth in the claims 1+.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Mr. Peter Ludwig on December 21, 2004 to request an oral election to the above restriction and election of species requirements, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and species to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

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claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen J. Lee, Ph.D. whose telephone number is 571-272-3446. The examiner can normally be reached on M-F; 9a.m.-6p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sjl

A handwritten signature in black ink, reading "Bruce Campell". The signature is written in a cursive, flowing style.

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600